IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:
YEHOSHUA SHACHAR

SERIAL NO. : 10/614,685

FILED: JUL. 3, 2003

FOR: METHOD AND APPARATUS FOR PIEZOELECTRIC LAYER-WISE PUMP AND VALVE FOR USE IN LOCAL ADMINISTRATION OF BIOLOGICAL RESPONSE MODIFIERS AND THERAPEUTIC AGENTS

Examiner: Andrew Gilbert

Group Art Unit: 3767

INTERVIEW SUMMARY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

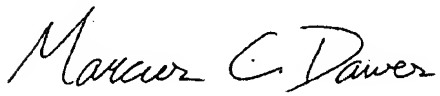
In response to the Examiner interview which took place on May 18, 2009, please record the substance of the interview as follows:

1. A brief video presentation of the invention was shown.
2. Claim 1 was discussed.
3. U.S. Patent 6,206,914 ("Soykan") was discussed.
4. See attached document for identification of the principal proposed amendments discussed.
5. See attached document for principal arguments presented to Examiner.

6. See attached document for a general indication of other pertinent matters discussed.

7. See Interview Summary Form completed by the Examiner for general results or outcome of the interview.

Respectfully submitted,



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TABULAR COMPARISON OF PROPOSED CLAIMS FOR DISCUSSION AT INTERVIEW ON MAY 18, 2009, 10:30AM

1. Case 1- parent

IN RE APPLICATION OF:
SHACHAR
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Claim 1 rejected over Soykan in view of Patterson in further view of Marshall.

Amended Claim	Office Action 1/23/2009	Primary Distinctions
1. An implantable apparatus for infusing a plurality of medicating agents to a specific desired location at a tumor site for nonsystemic treatment of a tumor, when implanted within a patient's body, comprising:		• Soykan is a vascular systemic treatment apparatus and method and is not operable for tumors.
an implantable pouch having ~~multiple~~ a plurality of collapsible and disintegratable chambers composed of a bioabsorbable material, the pouch comprising a scaffolding ~~comprised of collagen~~ forming a matrix capable of degrading over time, and a synthetic human skin for substantially enclosing the pouch, the chambers being	Soykan discloses an implantable apparatus comprising: an implantable pouch (col 3, lns 6-31; col 8, lns 63-67; col 9, lns 38-60; col 10, lns 4-8; col 12, lns 51-65; col 13, lns 16-28; col 14, lns 26-39; col 15, lns 5-12; col 16, lns 23-27, lns 42-61) having multiple collapsible chambers	• Soykan discloses cells or nanocubes, not pouches. • Soykan does not have a scaffolding covered by a synthetic human skin. • Soykan's cells and nanocubes cannot store amounts of agent sufficient for tumor treatment. • Soykan cannot provide treatments

structurally defined by the matrix, each chamber having a volume for storing a corresponding one of the plurality of the medicating agents in a macroscopic amount and for a duration sufficient for tumor treatment including relatively long durations, and wherein the chambers and the synthetic human skin are arranged and configured to substantially completely collapse and disintegrate within the patient's body with depletion of the plurality of medicating agents which is selectively dispensed from the chambers;	composed of a bioabsorbable material, the pouch comprising a scaffolding (col 9, lns 9-37; wherein the stent is disclosed as being polymeric and bioabsorbable;) capable of degrading over time, and a synthetic skin or enclosing the pouch; and multiple medicating agents disposed in said collapsible chambers (col 4, lns 18-32; col 8, lns 56-67, col 9, lns 35-37; col 9, lns 38-59, col 12, lns 51-65;	for a duration sufficient for tumors including relatively long durations due to the limited storage capacity of the cells and nanocubes. • Soykan does not schedule disintegration of the cells and nanocubes at all let alone to match the duration of the dispensing of the agents. • Tumor treatments over relatively long durations are enabled and not only acute episodes such as acute cardiac occlusions as in Soykan
where the plurality of ~~multiple~~ medicating agents ~~disposed~~ are stored in ~~said~~ corresponding ones of the plurality of collapsible chambers;	wherein each of the microscopic containment vehicles forms a chamber and each of the containment vehicles is capable of containing various cells and therapeutic agents);	
multiple implantable piezoelectric pumps of celluloid material fabricated in the pouch which pumps form~~s~~ a skeleton for the pouch, the pumps being configured to transfer the medicating agents to ~~said~~ the patient;	multiple implantable piezoelectric pumps (col 4, lns 18-32; col 12, lns 51-65; col 13, lns 16-27; col 14, lns 26-39) fabricated in the pouch which forms a skeleton of the pumps, the pumps being configured to transfer medicating agents to said patient (col 4, lns 18-32; col 12, lns 51-65; col 13, lns 16-27; col 14, lns 26-39); and	• Soykan's pumps are not made of a biological material, celluloid. pumps of celluloid material fabricated in the pouch which pumps form a skeleton for the pouch is a structure not shown for nanocubes or cell coatings in Soykan
where the synthetic human skin is an	an implantable, biocompatible and	• There is no human skin

implantable and bioabsorbable skin substitute ~~comprising a porous matrix of fibers of cross-linked tendon collagen and a chondroitin sulfate with a layer made of synthetic polysiloxane polymer covering the pouches and pumps; and~~	bioabsorbable skin (col 9, lns 38-60, col 10, lns 4-col 11, lns 14) covering the pouch and pumps; and	substitute in Soykan.
at least one implanted sensor to measure a local homeostatic response related to at least one of the plurality of medicating agents; and	with a memory	
an implanted control circuit on a biodegradable substrate housed within and implanted at the site of implantation of the pouch and proximate to the pumps to control optimal local ~~proper~~ dosing amounts of each of the medicating agents and scheduling of the medicating agents in a closed loop control mode so that control of the operation is performed autonomously as determined by adjustable values of locally sensed homeostatic parameters at the treatment site,	an implanted control circuit housed within the pouch (col 4, lns 18-32, col 13, lns 16-27, col 14, lns 10-39, col 15, lns 4-24, col 16, lns 18-61; Fig 2a; Fig 5;) to control proper dosing and scheduling of said medicating agent in a closed loop control mode so that control of the operation of the system is performed autonomously as determined by locally sensed homeostatic parameters (col 3, lns 6-31; col 8, lns 63-67; col 9, lns 38-60; col 10, lns 4-8; col 12, lns 51-65; col 13, lns 16-28; col 14, lns 26-39; col 15, lns 5-12; col 16, lns 23-27, lns 42-61).	• The claimed control circuit implanted at pouch implant site provides optimal local control performed autonomously as determined by adjustable values of locally sensed homeostatic parameters at the treatment site – Soykan shows only a transforming circuit with no control ability at the implant site. Soykan's timing control circuit is in a subdermal chest implant. • Dosing amounts of medication agents are autonomously controlled and not just timing of "a potent dose" as in Soykan
where the control circuit controls at least one of the piezoelectric pumps to modify the state of the tumor in response to measurements from the implanted sensor, and where the control circuit controls and selectively		

adjusts the scheduling of the amounts of the medicating agents which are delivered in response to selective user commands delivered to the control circuit and alterable during a treatment process after implantation.		

Patterson was cited to show scaffolding composed of collagen forming a matrix capable of degrading over time (col 4, lns 28-51) for the purpose of maintain the device in a certain position in the body during treatment and then degrading to avoid surgical risks associated with removing the device after treatment.

- Patterson does not schedule disintegration of the tube 20 to match the duration of the dispensing of an agent, but states that it "might dissolve in 9 – 12 months".

Marshall was cited to show a porous matrix of fibers of cross-linked tendon collagen and a chondroitin sulfate with a layer made of synthetic polysiloxane polymer (col 7, lns 19-35) for the purpose of providing a matrix scaffolding for an implant that promotes healing and infiltration of fibroblasts, capillaries, and other natural body healing responses.

- The analogous limitations in claim 1 have been deleted so that Marshall is no longer relevant to the claim.